# EXHIBIT 1

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April 18, 2023

**CONTAINS MATERIAL MODERNA DESIGNATED HIGHLY CONFIDENTIAL – ATTORNEY'S EYES ONLY**

**Via Email**

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Re: *Arbutus Biopharma Corporation and Genevant Sciences GmbH v. Moderna, Inc. and ModernaTX, Inc.*, Case 1:22-cv-00252-MSG (D. Del.)

Dear Mark:

I write to follow-up on Plaintiffs' March 3, 2023 letter and our subsequent meet-and-confers on March 8, 14, 22, and 29, 2023 and April 4, 11, and 12, 2023, with respect to Moderna's core technical document production. We will write separately regarding Moderna's responses to Plaintiffs' Requests for Production ("RFP") responses in light of our meet-and-confers, as well as Moderna's interrogatory responses.

As you know, Plaintiffs have sought Moderna's core technical documents in this case for nearly ten months—since July 2022. Plaintiffs first sought them after serving Plaintiffs' Initial Identification of Asserted Patents, Accused Products, and Damages model. Moderna refused to produce any documents at that time. *See, e.g.*, Email from J. Shaw dated July 27, 2022. Even before then, prior to this litigation, Plaintiffs requested samples and other non-public information relevant to the Accused Product. Moderna denied those requests. *See* D.I. 35 at 45. Again, in December 2022, Plaintiffs served their RFPs directed to Moderna's regulatory submissions, including Moderna's complete BLA, and other technical information and analytical testing Moderna has performed (or had performed by third-parties) with respect to the Accused Product. Moderna has not produced the requested documents.

Despite Moderna's extensive notice of the information sought by Plaintiffs, its core technical document production on February 10, 2023, constituted just a small fraction of

Moderna's BLA. As set forth in Plaintiffs' March 3 letter, Moderna did not take the standard and straight-forward step of producing its complete BLA No. 125752. Nor did Moderna even produce all versions and modifications of its specifications or the complete body of its regulatory submissions and/or communication with FDA explaining its basis and/or reasons for changing those specifications. Moderna also did not produce its complete IND No. 19745 and EUA No. 27073. While Moderna has complained of the voluminous nature of its regulatory filings, such filings appear to reside in a central electronic document management system ("eDMS") as shown on the face of nearly every "core technical document" Moderna produced. The production of these materials is routine discovery that Moderna ostensibly already provided in *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc.*, C.A. No. 22-cv-335-CFC (D. Del.), making Moderna's delay even more egregious.

As of the date of this letter—less than a week before the due date for Plaintiffs' initial infringement contentions—Moderna has finally and purportedly produced its complete BLA. *See* Letter from M. McLennan to A. Sheh (Apr. 18, 2023). Plaintiffs plainly have not been able to review this belated document production, and Moderna's production of its BLA now simply underscores the deficient nature of its core technical document production on February 10, 2023.

The limited nature of Moderna's core technical production and Moderna's RFP responses also indicate that Moderna has failed to produce all of its analytical testing of the Accused Product. Moderna's RFP responses have limited the scope of analytical tests it has agreed to produce to only a subset of the testing shown in its BLA (which is has not completely produced), and on our meet-and-confers, Moderna has declined even to identify what other tests it has performed. Instead, Moderna has complained about the number of tests of the Accused Product that are potentially implicated and the proportionality for certain tests, *e.g.*, testing related to the pH or microbiological testing. But there appears to be no dispute that at least with respect to the Accused Product, any testing Moderna has done (or had done by or with third-parties) related to the lipid molar ratio or structure of Moderna's lipid nanoparticles implicated in this case, is highly relevant and proportional to this litigation, including with respect to the variation in the lipid molar ratio between different batches of Moderna's Accused Product, as well as within individual batches. *See, e.g.*, Plaintiffs' RFP 32; *see also, e.g.*, Plaintiffs' RFPs 8, 11, 13, 15, 17–20, 24–27, 30–31, 33, 34, 38, 48, 73, 84, 89. We understand that you are investigating Plaintiffs' requests regarding analytical testing including with respect to Plaintiffs' RFPs, and we will address Moderna's RFP responses (and our subsequent meet-and-confers) in separate correspondence. For present purposes, however, Moderna's core technical document production lacks the information requested regarding analytical testing, and remains deficient as a result.

Similarly, notwithstanding Moderna's contrary position on our meet-and-confers, the manufacturing process of the Accused Product is highly relevant, and Moderna has not produced complete set of in-process testing or documents related to the effect of Moderna's manufacturing process on the molar ratio of its lipid nanoparticles. *See, e.g.*, Plaintiffs' RFPs 5, 8, 11, 13, 15–21, 23–27, 30–31, 33–34, 38, 48, 73, 84, 89. The relevance and proportionality of this information is not reasonably subject to dispute. *See, e.g.*, MRNA-GEN-00018729 at *18734–36; MRNA-

GEN-00034458 at *34467–71. Moderna's failure to produce this information renders its core technical document production deficient for this reason as well.

As Plaintiffs' March 3 letter also raised, Moderna's core technical document production lacked certificates of analysis and batch records for the batches of the Accused Product Moderna has made to date. In response to Plaintiffs' letter, Moderna produced just 64 additional certificates of analysis—which Plaintiffs, not Moderna, had identified based on the limited information in Moderna's core technical production. This is despite Moderna having informed Plaintiffs that Moderna has made thousands of batches, indicating that thousands of certificates remain unproduced. Since then, Moderna has not produced further certificates or batch records, nor has it provided substantive response to Plaintiffs' Interrogatory Nos. 6 and 11, depriving Plaintiffs of even a basic accounting of the infringing units that Moderna has manufactured, distributed, and sold to date. Plaintiffs will address the deficiencies in Moderna's interrogatories in separate correspondence. Yet again, however, Moderna's failure to produce highly relevant documents and information continues to prejudice Plaintiffs.

Finally, we understand that Moderna continues to investigate its ability to produce samples. To date, despite your assurances that Moderna will produce samples from a recently manufactured batch pending Moderna's investigation and the parties' resolution of the scope of sample production, Plaintiffs have not received any samples. *See, e.g.*, RFPs 98–99. Moderna's efforts to provide samples—albeit years after they were first requested—is appreciated, but the lack of samples continues to prejudice Plaintiffs.

Moderna's sweeping and continued failure to produce basic technical discovery about its product has prejudiced, and continues to prejudice, Plaintiffs' ability to litigate this case and prepare their initial infringement contentions. In view of the foregoing, Plaintiffs reserve all right, in light Moderna's deficient core technical document production and failure to timely produce any samples, to modify, amend, and supplement their infringement contentions, including with any information that Moderna just produced today. Plaintiffs further reserve the right to raise additional deficiencies in Moderna's discovery responses and document production as our review and discovery continues. We renew our requests that the above information and samples be produced without any further delay.

Sincerely,

Anthony Sheh

cc: Counsel of Record